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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,897	07/05/2005	Manne Satyanarayana Reddy	BULK 3.3-017	1563

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EXAMINER	
HAVLIN, ROBERT H	
ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
05/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patpros@drreddys.com

Office Action Summary	Application No.	Applicant(s)	
	10/516,897	REDDY ET AL.	
	Examiner	Art Unit	
	ROBERT HAVLIN	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,27-30 and 36-47* is/are pending in the application.

4a) Of the above claim(s) *1-7,13-24,27-30 and 36-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims: Claims 1-24, 27-30, and 36-47 are currently pending.

IDS: The IDS dated 2/23/09 was considered.

Election/Restrictions

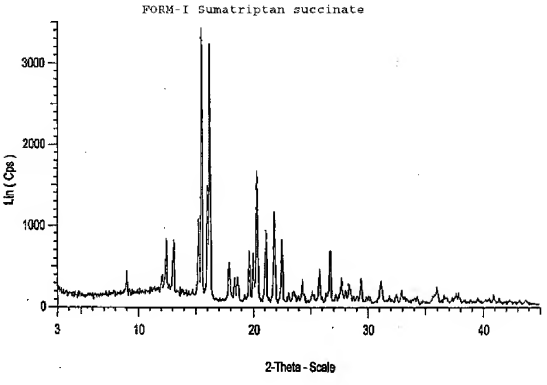
1. Applicant's election with traverse of III (claims 8-12) in the reply filed on 2/23/09 is acknowledged. The traversal is on the ground(s) that "the pending claims relates to one of only two possible chemical compounds" and a search would not be burdensome. This is not found persuasive because the search required for one crystalline for is distinct from a search for another crystalline form due to the different processes involved. In addition, applicant is claiming different crystalline forms of the compound alleged to be non-obvious over the prior art crystalline forms, therefore the restriction among crystalline forms, methods of using, and methods of making is proper. Applicant also asserts that the proper restriction practice for this application is unit of invention; however the restriction would be identical due to the fact that the technical feature linking the claims is simatriptan succinate which is known in the art in Oxford et al. (US 5,037,845). Therefore, the technical feature linking the claims does not constitute a special technical feature under PCT Rule 13.2. Accordingly, the claims lack unity of invention, and restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-7, 13-24, 27-30, and 36-47 are hereby withdrawn as reading on a non-elected invention.

2. Subsequent to the prior office actions, art was published showing the X-ray powder diffraction data for the pure form of sumatriptan succinate (Yang, et al. Pharmaceutical Research, Vol. 25, No. 9, Sep. 2008, pages 2012-18), the reference is used only to support the assertion that the product of Oxford et al. is identical to the claimed product. The comparison below of the instant application Figure 1 with Yang et al.'s pure sumatriptan succinate confirms the examiner's assertion in the prior office actions that a comparison of the X-ray powder diffraction data from the pure form of sumatriptan succinate with "Form-I" might show they are the same product. The positions of the peaks and the intensities are well within the experimental error for the method. Therefore, there is a substantial certainty that the product taught by the prior art reference of Oxford anticipates the claims because the X-ray powder diffraction data is the same, the method used in preparing the samples are the same, and applicant has provided no evidence distinguishing the claimed product from the prior art.

FIG. 1



Yang *et al.*

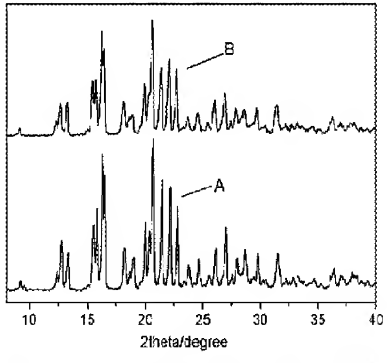


Fig. 9. XRD patterns of **A** standard and **B** ultrafine sumatriptan succinate obtained under optimum conditions.

Claim Rejections - 35 USC § 103

3. Claims 8-12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Oxford et al. in view of Brittain ("Polymorphism in Pharmaceutical Solids", V. 95, New York, Marcel Dekker, Inc., 1999) and further in view of Dorsey (John G. Dorsey, "Liquid chromatography", in AccessScience@McGraw-Hill, http://www.accessscience.com, DOI 10.1036/1097-8542.386200, last modified: June 3, 2002) and Vogel ("Practical Organic Chemistry:, 3rd edition, 1966, Wiley, New York).

4. The important points of the factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are partially *reiterated* below:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The instant claims read on the process for making a product ("Form-I" of sumatriptan succinate) comprising the following steps (from claim 8):

a. treating highly pure sumatriptan base in a ketone or alcoholic solvent (or mixtures thereof),
b. Add succinic acid to the mixture,
c. (optional)
d. Cooling the mixture to 0-35°C,
e. isolating the solid and drying it at 50-100°C.

"Form-I" requires (from page 6 of the instant specification):

> "… treating Sumatriptan in polar solvents such as ketones or ethers or esters or alcohols followed by addition of Succinic acid at reflux temperature and further cooling to ambient temperature to get the desired crystalline form."

1. Determining the scope and contents of the prior art.

Oxford teaches methods of making sumatriptan succinate in solid form. For example, example 19 teaches the following:

EXAMPLE 19

Compound with succinic acid (1:1)

A hot clarified solution of succinic acid (1.26 g) in IMS (10 ml) as added to a stirred clarified solution of the product of Example 3 (3.14 g) in IMS (60 ml) at 70°. Solid began to crystallise out almost immediately, and the mixture was allowed to cool to 30°. The stirred mixture was further cooled in an ice-bath (45 min). The solid was filtered off, washed with cold ethanol (35 ml) and dried in vacuo to give the title compound (4.17 g) m.p. 164°-165°. T.l.c. (D) Rf 0.7 (IPA, Ce^{IV}).

^1H n.m.r. and g.l.c. indicate the product contains 5.52% w/w ethanol (0.52 mol)

Analysis Found: C,51.7; H,6.95; N,9.8. $C_{14}H_{21}N_3O_2S.C_4H_6O_4.0.52C_2H_6O$ requires C,52.25; H,6.95; N,9.6%.

wherein IMS is methylated spirits (comprising ethanol and methanol).

2. Ascertaining the differences between the prior art and the claims at issue.

The difference between Oxford and the claim 8 is the drying temperature of 50-100°C while the prior art merely dries in vacuo.

The difference between Oxford and the claims 9-11 is the drying temperature of 50-100°C while the prior art merely dries in vacuo and the choice of solvent of step (a). The prior art teaches IMS, while the instant claims are for acetone, THF, and ethyl acetate for claims 9-11, respectively.

The difference between Oxford and the claim 12 is the drying temperature of 50-100°C while the prior art merely dries in vacuo and the use of 99% pure by HPLC sumatriptan. The prior art does not indicate the level of purity of the base.

3. Resolving the level of ordinary skill in the pertinent art.

One of ordinary skill in the art of pharmaceutical development is well versed in the teachings of references such as Vogel. One of ordinary skill in the art would consider routine and well within their technical grasp altering the solvent, drying conditions, and purity level of the starting materials in any given pharmaceutical preparation.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

One of ordinary skill in the art routinely varies drying conditions for products and is described in Vogel. One of ordinary skill in the art routinely alters precipitation solvents to improve yield and properties of the resulting product as is also described in Vogel and Brittain and is generally well known in the art. One of ordinary skill in the art commonly uses HPLC as is described in Dorsey to provide highest purity level possible in starting materials of any reaction.

Thus applicant's argument is: one of ordinary skill in the art would not know how to modify the solvent and procedure taught by Oxford to arrive at the instant invention because they could not predict which solvent will work to make the claimed invention. This argument is not persuasive because varying drying conditions, precipitation solvents, and HPLC purity levels are all well within the technical grasp of one of ordinary skill in the art and are routinely employed to improve yield and the quality of the product produced. Furthermore, there is no evidence how these differences result in a product that is patentably distinct from the prior art as disclosed by Yang. Therefore, this rejection is **maintained**.

Conclusion

No claim is in condition for allowance. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Examiner, Art Unit 1626

/Rebecca L Anderson/
Primary Examiner, Art Unit 1626